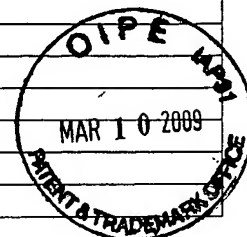


Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/501,335
		Filing Date	May 20, 2005
		First Named Inventor	Piero DEL SOLDATO
		Art Unit	1612
		Examiner Name	Barbara P. BADIO
		Attorney Docket Number	026220-00048
Sheet	1	of	4



NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Al Swayeh O.A. et al.; "Anti-oedema and antinociceptive effect of nitroprednisone and nitroflurbiprofen" Presented at the Joint Meeting of the British Pharmacological Society and the Societa de Portuguesa de Farmacologia, Porto; Portugal; 1999; Published in Br. J. Pharmacol; 1999; 127:84	
		Burgaud, J.L. et al.; "NO-Steroids: a class of new anti-asthmatic agents induced bronchodilation on guinea-pig trachea in vitro"; Presented at Proceedings of the British Pharmacological Society; Cambridge, UK; pgs. 5-7; January 2000; Published in Br. J. Pharmacol; 2000; 129:28P	
		Paul Clark M.J. et al.; "NCX-1015, a novel derivative of prednisolone with enhanced anti-inflammatory activity; Presented at Proceedings of the British Pharmacological Society, Cambridge, UK, January 5-7, 2000; Published in Br. J. Pharmacol.; 2000: 129-98P	
		Burgaud, J.L. et al.; "NO-Steroides: de nouveaux puissants anti-inflammatoires aux propriétés bronchodilatatrices; Presented at the NO 2000 Meeting; Paris, France; March 10, 2000	
		Paul Clark M.J. et al.; "A nitro-derivative of prednisolone (NCX-1015) possesses higher anti-inflammatory activities; Presented at Annual Meeting of Professional Research Scientists: Experimental Biology; 2000; San Diego; USA 15-18; April 2000; Published in FASEB-Journal; 2000; vol. 14; no. 4; p.A703	
		Fiorucci S. et al.; "A new nitric oxide steroid derivative (NCX-1015) with enhanced anti-inflammatory properties reduces colonic inflammation in mice; Presented at the DDW Meeting; San Diego; USA; 21-24; May 2000; Published in Gastroenterology; 2000; vol. 118; no. 4; Suppl. 2; Part 1; p. AGA A587	
		Di Filippo C. et al.; "Effects on blood pressure and heart rate of normotensive rats by chronic treatment with prednisolone 21-[(4'-nitrooxymethyl)benzoate]" Presented 11 th at International Conference on Advances in Prostaglandin's and Leukotriene Research; Florence, Italy 4-8; June 2000; Published in an abstract book Advances in prostaglandin and leukotriene research; 2000; p. 68	
		Mancini L. et al.; "Prednisolone, but not NCX 1015, activates osteoclast activity in an in vitro assay"; Presented 11 th International Conference on Advances in Prostaglandin and Leukotriene Research; Florence, Italy; 4-8; June 2000; Published in an abstract book Advances in prostaglandin and leukotriene research; 2000; p.90	
		Perretti M. et al.; "Nitro-prednisolone is more potent than prednisolone in experimental inflammation"; Presented at 11 th International Conference on Advances in Prostaglandin's and Leukotriene Research; Florence, Italy; 4-8; June 2000; Published in an Abstract book Advances in prostaglandin and leukotriene research; 2000; p. 92	
		Mancini L. et al.; "Nitric Oxide released by nitro-prednisolone, a new synthetic steroid, prevents steroid-induced bone resorption"; Presented at the 11 th International Congress of Endocrinology; Sydney, Australia; 29 Oct. -2 Nov. 2000	
		Del Soldato P.; "NO-releasing drugs, a novel class of very effective and safe compounds"; Presented at the 3 rd US-Taiwan Neuroscience Symposium on NO; New Orleans; Nov. 4 2000; Published in an abstract book US-Taiwan Neuroscience Symposium on NO, 2000; III.6	
		Keeble J. et al.; "The catabolism of NO-NSAIDs and other nitric oxide-releasing compounds in vitro"; Presented at Pharmacology Meeting; Vancouver, Canada; March 24-27 2001	
		Tallet D. et al.; "Inhibition by NO-salbutamol and NO-budesonide of the bronchoconstriction by methacholine in guinea-pigs perfused bronchiles"; Presented at Satellite Symposium XXX Congresso Nazionale SIF; Capri, Italy; May 11-12 2001	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/501,335		
		Filing Date	May 20, 2005		
		First Named Inventor	Piero DEL SOLDATO		
		Art Unit	1612		
		Examiner Name	Barbara P. BADIO		
Sheet	2	of	4	Attorney Docket Number	026220-00048

(Use as many sheets as necessary)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Roviezzo F. et al.; "NCX-1015: a potent NO releasing glucocorticoid with enhanced activation of the glucocorticoid receptor" Presented at Satellite Symposium XXX Congresso Nazionale SIF; Capri, Italy; May 11-12, 2001	
		J.L. Burguad; "NO-aspirin and NO-prednisolone: examples of very effective and safe NO-releasing compounds; Presented at 1 st Magna Graecia Medicinal Chemistry Workshop on New Perspective in Drug Research; Copanello, Italy; June 10-13, 2001; Published in abstract book First Magna Graecia Medicinal Chemistry Workshop on New Perspectives in Drug research; June 2001; page 36; Abstract reference:OC14	
		Tallet D. et al.; "Effect of NO-derivatives of salbutamol and budesonide in precontracted guinea-pigs bronchioles in vitro"; Presented at 3 rd Meeting of the Federation of the European Pharmacological Societies (EPHAR); Lyon, France; July 6-9 2001; Published in an abstract book Fundamental & Clinical Pharmacology; July 2001; vol. 15; suppl. 1; 9P047	
		Tallet D. et al.; "Inhibition by NO-salbutamol and NO-budesonide of the bronchoconstriction by methacholine in guinea-pigs perfused bronchioles; Presented at 5 th World Congress on Inflammation; Edinburgh, UK; September 22-26; 2001; Published in Inflammation Research; 2001; vol. 50; suppl. 3; A048, S200	
		Paul-Clark M.J. et al.; "Local and systemic effects of nitro-prednisolone (NCX 1015) in experimental arthritis"; Presented at 5 th World Congress on Inflammation; Edinburgh, UK; September 22-26, 2001; Published in Inflammation Research; 2001; vol. 50; suppl. 3; W14/02, S176	
		Turesin F. et al.; "Prevention of allergic inflammation by NCX 1015, a novel nitric oxide releasing glucocorticoid"; Presented at the 5 th World Congress on Inflammation; Edinburgh, UK; September 22-26, 2001; Published in Inflammation Research; 2001; vol. 50; suppl. 3; W25/03, S187	
		Roviezzo F. et al.; "Enhanced activation of the glucocorticoid receptor by nitro-prednisolone (NCX-1015)"; Presented at the 5 th World Congress on Inflammation, Edinburgh, UK; September 22-26, 2001; Published in Inflammation Research; 2001; vol. 50; suppl. 3, W14/03, S176	
		Burdsall J. et al.; "Nitroprednisolone is a potent suppressor of IL-1b and TNFA production by peripheral whole blood mononuclear cells when stimulated in vitro by LPS"; Presented at 9 th European Gastroenterology Week; Holland; October 6-10, 2001; Published in GUT; Nov. 2001; 49,2410	
		Smith, A.; "Anti-Inflammatories. No bones about it"; Nature Reviews Drug Discovery 2002; 1:173	
		Burdsall J. et al.; "Release of Nitric Oxide from Six Nitrosteroids by Tissue Esterases; Presented at Digestive Disease Week; San Francisco; USA; May 19-22, 2002; Published in Gastroenterology Supplement; April 2002; vol. 122(4); A-433:T1209	
		Peskar B.M. et al.; "NCX-1015, a Novel Nitric Oxide-Releasing Derivative of Prednisolone, Combines Potent Anti-Inflammatory Activity and Low Toxicity in the Rat Stomach Subjected to Ischemia-Reperfusion; Presented at Digestive Disease Week; San Francisco; USA; May 19-22, 2002; Published in Gastroenterology Supplement; April 2002; vol. 122(4); A-229:M891	
		Burdsall J. et al.; "Release of Nitric Oxide from Six Nitrosteroids by Tissue Esterases"; Presented at Digestive Disease Week; San Francisco; USA; May 19-22, 2002; Published in Gastroenterology Supplement; April 2002; vol. 122(4); A-433:T1209	
		Sardina M. et al.; "New NO-releasing compounds for the treatment of inflammatory airways diseases"; Presented at Satellite Meeting of the XIVth IUPHAR Meeting. New Drugs for the Respiratory Diseases V Meeting; San Diego; USA; July 3-5, 2002; Published in an abstract book New Drugs for the Respiratory Diseases V Meeting; San Diego; USA; July 3-5, 2002; p. 13	
		Keeble J.; "The cardiovascular effects and pharmacokinetics of NO-NSAIDs and other NO-releasing adduct drugs"; Presented at Satellite Meeting of the XIVth IUPHAR Meeting. New Drugs for the Respiratory Diseases V Meeting; San Diego; USA; July 3-5, 2002	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/501,335
		Filing Date	May 20, 2005
		First Named Inventor	Piero DEL SOLDATO
		Art Unit	1612
		Examiner Name	Barbara P. BADIO
		Attorney Docket Number	026220-00048
Sheet	3	of	4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Futter L.E. et al.; "Smooth Muscle Relaxant Effect of NO-NSAID in the Guinea Pig Ileum"; Presented at XIVth World Congress of Pharmacology; San Francisco; USA; July 7-12, 2002; Published in an abstract book XIV World Congress of Pharmacology, Abstract Volume; vol. 44; N°2(Suppl 1); 2514:A26	
		Del Soldato P.; "NO-Releasing Drugs, a Novel Class of very effective and safe compounds of Potential Interest to the Gastroenterologist"; Presented at XIVth World Congress of Pharmacology; San Francisco; USA; July 7-12, 2002; Published in an abstract book XIV World Congress of Pharmacology, Abstract Volume; vol. 44; N°2(Suppl 1); 8.2:A4	
		Orgini E. et al.; "Nuovi farmaci antiinfiammatori che rilasciano ossido d'azoto (NO)"; Presented at XVI Convegno Naz. Divisione Chimica Farmaceutica; Sorrento, Italy; September 18-22, 2002	
		Fiorucci S. et al.; "NCX-1015, a nitric-oxide derivative of prednisolone, enhances regulatory T cells in the lamina propria and protects against 2,4,6-trinitrobenzene sulfonic acid-induced colitis in mice"; Proc Natl Acad Sci USA; 2002; 99:15770-5	
		Paul-Clark M.J. et al.; "Potent antiarthritic properties of a glucocorticoid derivative, NCX-1015, in an experimental model of arthritis"; Proc Natl Acad Sci; USA; 2002; 99:1677-82	
		Paul-Clark M.J. et al.; "Effects of a novel NO-releasing glucocorticoid (NCX-1015) in a rat model of gout"; Presented at BPS Meeting; Brighton, UK; January 8-10, 2003; Published in Br J Pharmacol; April 2003; vol. 138; P.76	
		Paul-Clark M.J. et al.; "Anti-arthritis properties of an NO-donating glucocorticoid, NCX-1015"; Presented at Experimental Biology. Translating the Genome 2003; San Diego; USA; April 11-15, 2003	
		Nevin B.J. et al.; "Comparative Effects of Budesonide and Budesonide-NO Against Leukocyte Influx Following Lipopolysaccharide (LPS) Administration in Guinea-Pigs"; Presented at the ATS American Thoracic Society; Seattle, Washington; May 16-21, 2003	
		Perretti M. et al.; "Generation of innovative anti-inflammatory and anti-arthritis glucocorticoid derivatives that release NO. The nitro-steroids"; Dig Liver Dis 2003; 35; S. 41-48	
		Sawka N. et al.; "NCX-1015, a nitric oxide-releasing derivative of prednisolone, but not prednisolone protects against ischemia-reperfusion damage induced by naproxen or rofecoxib in the rat stomach"; Presented at the Digestive Disease Week 2003; Orlando; USA; May 17-22, 2003; Published in the DDW abstract book; 2003; A-242:S. 1198	
		Del Soldato P.; "NO-releasing drugs, a novel class of very effective and safe compounds of potential interest to the rheumatologist"; Presented at the 6 th World Congress on Inflammation; Vancouver, Canada; August 2-6, 2003; Published in Inflamm Res; July 2003; 52; S109 :IS-50	
		Paul-Clark M.J. et al.; "The enhanced anti-inflammatory properties of nitro-prednisolone (NCX-1015) is linked to post-translational modification of the glucocorticoid receptor"; Presented at the 6 th World Congress on Inflammation; Vancouver, Canada; August 2-6, 2003; Published in Inflamm Res; 2003; 52: S126:18.5	
		Paul-Clark M.J. et al.; "Glucocorticoid Receptor Nitration Leads to Enhanced Anti-Inflammatory Effects of Novel Steroid Ligands"; J Immunol; 2003; 171: 3245-3252	
		Ferrario M. et al.; "Synthesis of nitro esters of prednisolone, new compounds combining pharmacological properties of both glucocorticoids and nitric oxide"; Presented at Polish-Austrian-German-Hungarian Joint Meeting on Medicinal Chemistry; Krakow, Poland; October 15-18, 2003	
		Mallei A. et al.; "NCX 1015, A NO-releasing derivative of prednisolone, improves recovery of function after spinal cord injury"; Presented at the 33 rd Annual Meeting of the Society for Neuroscience; New Orleans; USA; November 8-12, 2003	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/501,335		
		Filing Date	May 20, 2005		
		First Named Inventor	Piero DEL SOLDATO		
		Art Unit	1612		
		Examiner Name	Barbara P. BADIO		
Sheet	4	of	4	Attorney Docket Number	026220-00048

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Baraldi P.G. et al.; "Synthesis of Nitro Esters of Prednisolone, New Compounds Combining Pharmacological Properties of Both Glucocorticoids and Nitric Oxide"; J Med Chem; 2004; 47: p. 711-719	
		Di Filippo C. et al.; "The distinct alterations produced in cardiovascular functions by prednisolone and nitro-prednisolone (NCX-1015) in the rat highlight a causal role for endothelin-1"; J Pharmacol Exp Ther; 2004; 310: p. 1133-1141	
		Nevin BJ et al.; "Comparative effects of inhaled budesonide and the NO-donating budesonide derivative, NCX 1020, against leukocyte influx and airway hyperreactivity following lipopolysaccharide challenge"; Pulm Pharmacol Ther 2004; 17: p. 219-232	
		Mallei A. et al.; "The nitrosteroid NCX 1015, a prednisolone derivative, improves recovery of function in the spinal cord injury rat model"; Brain Res 2005; 1062: p. 16-25	
		Armogida M. et al.; "Preliminary evidence of bronchodilating activity of TPI 1020 (NO-budenoside) in humans"; Presented at European Respiratory Society; Munich, Germany; September 2-6, 2006	
		Brault J. et al.; "Effects of TPI-1020, a NO-donating derivative of budesonide, on neutrophil migration and activation in vitro and in vivo models of COPD"; Presented at the American Thoracic Society Meeting; San Francisco, CA; USA; May 19-23, 2007	
		"TPI 1020: a novel nitric oxide-donating molecule with respiratory anti-inflammatory molecule with nitric-oxide donating mechanism and bronchodilating properties in animal models of neutrophilss-mediated diseases of the airways"; Presented at APPQ-RHN symposium; Montreal, Quebec, Candada; November 8-10, 2007	
		Oliveira MS et al.; "Suppressive effects of nitric oxide-releasing prednisolone NCX 1015 on the allergic pleural eosinophil recruitment in rats"; Clin Exp Allergy 2008; in press	
		Nicox press release; December 23, 2008	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.